

## DETAILED ACTION

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 8-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Harris (US Patent No. 6,540,724 B1) (Hereafter, Harris) in view of Hausslein (US Patent No. 6,022,144) (Hereinafter, Hausslein) and further in view of Wolzinger (US Patent No. 5,605,546) (Hereinafter, Wolzinger).

With regards to claim 1, Harris discloses (figures 1-8) a removable protective cover for an exposed portion of a medical device extending along a longitudinal axis from a body, the cover comprising: a housing defining an opening along a single edge comprising a first and a second edge portion, the edge portions in opposing relationship and joined at the respective ends to receive the exposed portion, the edge intersecting the axis, and the edge being sealable to enclose the exposed portion within the housing (figure 3). However, Harris does not disclose the edge being biased for operation between a closed position and an open position by a spring member in each of the edge portions. Hausslein, discloses the edge being biased for operation between a closed position and an open position by a spring member in each of the edge portions (figure 3). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the cover of Harris as disclosed by Hausslein for making the cover easy to operate.

With regards to claim 2, Harris and Hausslein disclose the cover claimed in claim 1, and further disclose the housing comprising a pair of opposing walls defining a sealable pocket (paragraph [0005]).

With regards to claim 3, Harris and Hausslein disclose the cover claimed in claim 2, and further disclose the pocket being made of one or more flexible materials (paragraph [0005]).

With regards to claim 4 and 17, Harris and Hausslein disclose the cover claimed in claim 3 and 16. However, Harris does not disclose the one or more flexible materials being water impermeable. Hausslein discloses (column 12, line 54) the one or more flexible materials being water impermeable. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the protective cover of Harris as disclosed by Hausslein to make the cover fluid tight.

With regards to claim 5, Harris and Hausslein disclose the cover claimed in claim 1, and further disclose the edge being operable between a closed position and an open position by operation of a single hand.

With regards to claim 8, Harris (abstract) and Hausslein disclose the cover claimed in claim 1, and further disclose it comprising adhesive along the first edge to releasably seal the opening.

With regards to claim 9, Harris (see, column 1, line 65 to column 2 lines 2) and Hausslein disclose the cover claimed in claim 1. However, they do not disclose the edge being defined along a single plane in sealable contact with the body. Wolzinger

discloses (52, 54, 56, 66) adhesive seals. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the protective cover of Harris (see, column 1, line 65 to column 2 lines 2) and Hausslein as disclosed by Wolzinger to secure the cover to the body.

With regards to claim 10, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 9, and further disclose, the plane comprising a band of adhesive encircling the opening for releasably securing the cover directly to the body, about an entry point through which the medical device extends into the body (Harris, column 4, lines 3-19).

With regards to claim 11, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 9, and further disclose the plane comprising a band for releasably securing the cover directly to the body (column 4, lines 8-19).

With regards to claim 12, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 11, and further disclose the band comprising an adhesive to secure the cover to the body, thereby forming a barrier about the entry point (column 4, lines 3-19).

With regards to claim 13, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 1, and further disclose it further comprising a display for treatment information (column 4, lines 3-19).

With regards to claim 14, Harris, Hausslein and Wolzinger disclose the kit for covering an exposed portion of a medical device extending outwardly from a body, the kit comprising: a first housing comprising the housing of claim 1; and a second housing

receiving the first housing, the second housing being releasably securable to the body, about an entry point through which the medical device extends into the body.

With regards to claim 15, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 14, and further disclose the first housing defining a pocket comprising a first set of two opposing walls.

With regards to claim 16, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 15, and further disclose the first set of opposing walls being made of one or more flexible materials.

With regards to claim 18, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 14, and further disclose the second housing comprising a band for releasably securing the second housing directly to the body (Harris, column 4, lines 8-19).

With regards to claim 19, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 18, and further disclose the band comprising an adhesive to secure the second housing directly to the body, about an entry point through which the medical device extends from the body (Harris, column 4, lines 8-19).

With regards to claim 20, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 19, and further disclose the band forming an impermeable barrier about the entry point.

With regards to claim 21, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 20, and further disclose, the second housing comprising a second set

of opposing walls made from one or more flexible materials to form an impermeable barrier.

With regards to claim 22, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 14, and further disclose the first housing being visible through the second housing when the two housings are secured to the body.

With regards to claim 23, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 1, and further disclose the housing defining a second opening opposite the single edge, the second opening being reclosable when the protective cover is secured to the body.

With regards to claim 24, Harris, Hausslein and Wolzinger disclose the cover claimed in claim 23, and further disclose the second opening being defined along a second single edge, the second edge intersecting the axis, and the second edge being sealable to enclose the exposed portion within the housing.

With regards to claim 25, Harris, Hausslein and Wolzinger disclose a method of providing a removable, resealable sterile (see Wolzinger, column 6, lines 43-49) protective cover for an exposed portion of a medical device extending along a longitudinal axis from a body, the cover comprising a housing according to claim 1, the housing defining an opening along a single edge, the method comprising: introducing the exposed portion across the single edge, into the housing; positioning the exposed portion of the medical device within the housing so that the edge intersects the axis; sealing the edge to enclose the exposed portion within the housing; and securing the housing relative to the body.

With regards to claim 26, Harris, Hausslein and Wolzinger a method of providing a removable, resealable sterile protective cover as claimed in claim 25, and further disclose it comprising the step of securing the housing to the body via an adhesive band about the opening.

With regards to claims 27, Harris, Hausslein and Wolzinger disclose the cover and methods claimed in claim 25 and further disclose the edge being biased for operation between a closed position and an open position.

With regards to claims 27, Harris, Hausslein and Wolzinger disclose the method claimed in claim 25, and further disclose it comprising the step of securing the housing relative to the body by releasing a biasing member positioned along the single edge to engage the exposed portion.

### ***Response to Amendment***

The present communication responds to the Amendment of 01/09/2008. By this communication, the specification, drawings and claims 1, 14 and 25 were amended and claims 6 and 7 were canceled. The amendments did not appear to add new matter. Claims 1-27 are pending. The rejection(s) are as stated.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's argument that biasing elements is not disclosed, a recitation of the intended use of the claimed

invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Conclusion***

References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 are cited in their entirety.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/  
Examiner  
Art Unit 3767

MJA  
4/10/2008  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767